

EXHIBIT H

BUSINESS

This medical device rivalry is getting a bit heated

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ERIC WIEFFERING Physician/inventor Scott Augustine isn't given to nuance.
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Once, outside a courtroom, he denounced a federal investigation of Medicare fraud, saying, "The government didn't have a case."

Note that this declaration came moments after Augustine pleaded guilty to a misdemeanor and agreed to pay a \$2 million fine. Maybe that gives you a sense for the kind of intensity Augustine brings to his latest fight, a battle for shelf space in hospital operating rooms around the world.

Augustine says he has a new, better way to way to keep patients warm during surgery. He's going up against a safe and proven technology currently used by 90 percent of U.S. hospitals.

But this isn't your typical entrepreneur with a better-mousetrap story.

For one thing, Augustine's competitor is Maplewood-based 3M, which last year paid \$810 million to buy Arizant, an Eden Prairie firm whose Bair Hugger blankets and gowns were used in about 22 million surgeries last year.

Clinical studies have shown that keeping a patient warm during surgery reduces bleeding, speeds recovery and keeps patients more comfortable. Bair Hugger accomplishes this through warmed air carried through a hose that attaches to the garments or blankets used by the patient.

The inventor of the Bair Hugger and the man who helped fund some of that early, pioneering research on the value of patient warming? Why that would be Augustine, who has more than 150 patents to his name. He left Arizant, which used to be called Augustine Medical, in 2002 after a dispute with other board members. His new product, in which he claims to have invested \$23 million, is called HotDog. It's essentially an electric blanket that incorporates high-tech material originally developed for stealth aircraft.

"Forced air is my baby, and I love my baby," Augustine said. "But I believe it's the introduction of forced-air warming that has led to the increase in infections," particularly in patients receiving artificial joints or having medical devices implanted.

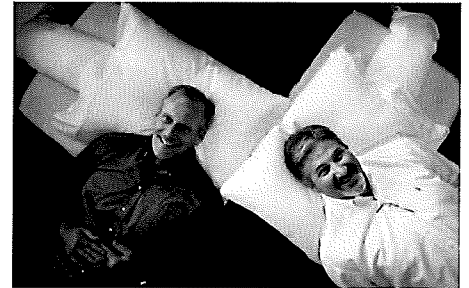
There's no clinical evidence to support that belief, a fact 3M's vice president of patient warming business, Robert Buehler, takes pains to point out. "The science is clear that forced-air warming is safe and effective," he said.

Since he can't make the claim that HotDog can lower infection rates -- that would require a long, expensive clinical trial and verification by the Food and Drug Administration -- Augustine is focusing on the air-flow dynamics of an operating room.

A video he's produced in a simulated surgical setting shows that waste heat spilling from the Bair Hugger combines with the presence of the surgeon and the lights to create a chimney effect. Air -- and potential contaminants -- are pulled from below the operating table and over the surgical field. At the end of the video, the narrator gravely intones, "I urge you to just say no to forced-air warming."

Augustine says it's a problem that he didn't know existed until he stumbled across it while testing another product, a pillowcase. "But when you think about it," he said, "it's really just seventh-grade science."

3M executives say these tactics and others -- such as a letter Augustine sent them last year (and shared with the New York Times) suggesting a coverup of the risks of forced-air warming -- smack of desperation.



(<http://stmedia.startribune.com/images/1ew1204.jpg>)
GLEN STUBBE, STAR TRIBUNE

Scott Augustine, left, CEO of Augustine Biomedical+Design, was testing a new pillowcase when he observed how forced-air...

"Scott isn't getting traction in the scientific community or the marketplace, so he's resorting to these nontraditional means" of winning product acceptance, Buehler said. Recently, a German court found that Augustine's marketing materials had violated that country's advertising standards, which are generally stricter in terms of the kinds of comparison claims that can be made.

Each company is also touting papers recently published in medical journals that reach opposite conclusions regarding the effect of forced air on airflow in the operating room. One says it's bad, the other says it's not, but each has flaws in its own right.

Ridgeview Medical Center in Waconia was an early test site for HotDog. Since switching from Bair Hugger in 2008, the hospital's reported rate of infection in knee-replacement surgery has fallen more than 81 percent.

Because Ridgeview undertook a number of steps to reduce infections, including hiring an infection control specialist, administrators are careful to say that there is no data to support a direct correlation between the use of Augustine's product and the drop in the infection rate. But the hospital now uses HotDog patient warming for all surgeries.

As a test site, Ridgeview didn't have to pay for the material, but the hospital's president says one of the most appealing things about HotDog is that its products are reusable.

"I can't say definitively that it would put a patient at risk to use forced-air warming," said Robert Stephens, Ridgeview's president. "Intuitively, though, any kind of air movement in an operating room would be a concern for us."

But a patient trial at Abbott Northwestern Hospital in Minneapolis never really got off the ground, said Carol Machemer, a nurse and patient care manager. Employees didn't like using it, and some patients objected to the strong plastic smell. Even the name was off-putting, she said.

The trial ended early, and the hospital continues to use the Bair Hugger on every surgical patient. "There is no concern that I'm aware of, on the part of staff or physicians, about the safety of forced-air warming," Machemer said.

Even so, Augustine says HotDog is taking business away from 3M and is on track to do up to \$15 million in sales next year. But, in a rare moment of humility, he acknowledged that it hasn't been easy.

"We're competing against a product that people absolutely love."

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